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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,055

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Craig D. Friedman

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54042

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08/18/2008

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

08/18/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,055	<b>Applicant(s)</b> FRIEDMAN ET AL.	
	<b>Examiner</b> Casey S. Hagopian	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7,9-12,61,63-69,72-76 and 79-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7,9-12,61,63-69,72-76 and 79-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 4/23/2008 and Supplemental Amendment/Remarks 5/13/2008. The supplemental reply filed on 5/13/2008 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii). The Office may enter a supplemental reply if the supplemental reply is clearly limited to:

- (A) Cancellation of a claim(s);
- (B) Adoption of the examiner suggestion(s);
- (C) Placement of the application in condition for allowance;
- (D) Reply to an Office requirement made after the first reply was filed;
- (E) Correction of informalities (*e.g.*, typographical errors); or
- (F) Simplification of issues for appeal.

The supplemental reply does not fall into any of the categories described above, thus the supplemental amendment was not entered.

Claims 1, 4, 6, 8, 13-60, 62, 70, 71, 77 and 78 are cancelled. Claims 84-110 are new. Claims 2, 7, 10, 68, 69, 82 and 83 are currently amended. Thus, claims 2, 3, 5, 7, 9-12, 61, 63-69, 72-76, 79-110 are pending.

### **MAINTAINED REJECTIONS**

No previous objections/rejections have been maintained from the Office Action dated 1/23/2008.

### ***Response to Arguments***

The cancellation of claim 8 renders the previous objection to said claim moot. Thus, the objection has been removed.

The cancellation of claim 6 and amendments to claims 7, 10, 68, 69, 82 and 83 render the previous rejections under 35 USC 112, 2<sup>nd</sup> paragraph of *those* claims moot. The cancellation of claim 6 also renders the Double Patenting warning moot. Thus, said 112 rejections and Double Patenting warning have been withdrawn.

Applicant's amendment dated 4/23/2008 renders the rejections under 35 USC 102 and 103 moot. Thus, said 102 and 103 rejections have been withdrawn. However, upon further consideration, new rejections are made under 35 USC 102 and 103 utilizing Thomson (US 2002/0018884 A1), Van Antwerp (US 2003/0031699 A1) and Pinchuk (USPN 5,229,431). See *New Rejections* below.

It is noted that claims 109 and 110 are effectively previous claims 68 and 69. Previous claims 68 and 69 were rejected under 35 USC 103 over the combination of Thomson and Pinchuk in the Office Action dated 1/23/2008. Applicant indicates that new claims 109 and 110 are distinguishable from the teachings of the prior art, however does not provides reasons as to why the claims are distinguishable over the prior art. See page 13 of Applicant's Remarks dated 4/23/2008. As such, the examiner is utilizing the same art rejection under 35 USC 103 over the combination of Thomson and Pinchuk but modifying the claim numbers from 68 and 69 to 109 and 110. See *New Rejections* below.

### **NEW OBJECTIONS/REJECTIONS**

After further consideration and in light of applicant's amendments submitted 4/23/2008, the following objections/rejections are newly added:

#### ***Claim Objections***

Claims 10 and 89 are objected to because of the following informalities: said claims include the limitation "the one or more therapeutic agents are selected from the group consisting of... and mixtures of two or more". The underlined portions are repetitive because "one or more" implies "mixtures of two or more". It is suggested that applicant remove the repetitive language. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

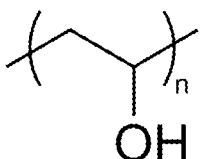
Claims 2, 3, 5, 7, 9-12, 61, 63-69, 72-76, 79-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 61, 84, 92 and 109 include the limitation "resilient". It is unclear what is meant by said limitation. Resilient to what? And to what extent? Also, the specification lacks a clear definition of what is intended by said limitation. As such, said limitation is indefinite.

Claims 2, 84 and 109 include the limitation "at least partially hydrophobic". The term is unclear because the limitation could mean that there is a block, graft or pendant

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included that is hydrophobic or it could include a typically "hydrophilic" polymer such as polyvinyl alcohol (PVA) that has a hydrophobic moiety in its backbone. The structure of PVA is provided below for applicant's convenience.



Effectively, said limitation includes hydrophilic, hydrophobic and amphiphilic polymers. Also, the specification lacks a clear definition of what is meant by said limitation. As such, said limitation is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 84, 86-97 and 100-108 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Thomson (US 2002/0018884 A1).

Thomson teaches a foam composite comprising reticulated hydrophobic polyurethane foam substrate that is coated with a coating comprising a hydrophilic

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polyurethane prepolymer (paragraph [0012]; Figure 1). Said hydrophilic coating can be a hydrophilic polyurethane foam coating (paragraph 0015). One embodiment comprises a coating of a mixture of a hydrophilic polyurethane and a hydrophilic hydrogel (paragraph [0130]). Said hydrogel can be based on polysaccharides including alginate, carrageenan, agar, etc. (paragraph [0130]). Said polysaccharides are well-known in the art as “biodegradable”. It is noted that claim 84 includes the limitation “the coating comprises a biodegradable polymer” and as such the examiner is taking into account the open language, i.e., the coating need not be fully biodegradable. Thomson also teaches embodiments that include an active ingredient in the hydrophilic coating (paragraph [0014]). Said active ingredients include pharmaceutical, enzymes and human cells (paragraph [0147]). Figure 20 illustrates a particular drug delivery embodiment. Thomson teaches void volumes of up to 98% and pore size from 4 to 100 pores per linear inch (ppi) (paragraph [0070]). Regarding the limitations of claims 104-106, absent of a showing of evidence to the contrary, said pore sizes taught by Thomson read on the pore sizes claimed. Regarding the limitations of claims 90 and 91, Thomson teaches various shapes (paragraph [0071]). It is also noted that generally limitations drawn to shapes are not accorded patentable weight (see MPEP 2144.04 (I) and (IV)(A)-(B)). Regarding the limitations of claims 86 and 92-97, said limitations are considered taught by the prior art, because the prior art teaches the claimed invention comprising the same materials. Regarding claims 101 and 102, Thomson contemplates coatings in the form of films and hydrogels (paragraphs [0092]-[0097] and [0130]). Regarding claim 103, the polyurethane coating and hydrogels mentioned previously

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read on non-biodegradable polymers as evidenced by paragraph [00179] of the instant specification. Thus, teachings of Thomson render the instant claims anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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Claims 85, 98, 99, 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Pinchuk (USPN 5,229,431).

Thomson teaches the elements discussed above.

Thomson is silent to including an active agent into the scaffold as well as the particular scaffold material containing polycarbonate polyurethane.

Pinchuk teaches a polycarbonate urethane foam suitable for medical prosthesis and implants (abstract). Said suitable medical prosthesis and implants include drug eluting matrices (col. 3, line 4).

One of ordinary skill in the art would have been motivated to include the particular material polycarbonate urethane because of its crack-resistant, elastomeric and pliable properties (abstract). A practitioner would have reasonably expected said material to withstand the stresses and degradation conditions once implanted in the body. One skilled in the art would have additionally expected inclusion of an agent within the matrix to effectively elute into the body. Thus, in Thomson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular material polycarbonate urethane as well as an active agent into a scaffold as suggested by Pinchuk.

Claims 2, 5, 7, 9-12, 61, 63-67, 72-74, 76, 79-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Van Antwerp (US 2003/0031699 A1).

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Thomson teaches the elements discussed above.

Thomson is silent to microspheres.

Van Antwerp teaches polymer coated implantable medical devices having a bioactive material posited in or on at least a portion of the coating layer, wherein the coating layer provides for controlled release of the bioactive material from the coating layer (abstract). Said coating can be hydrophilic or more specifically a hydrogel (paragraphs [0028], [0031] and [0035]). In a particular embodiment, Van Antwerp teaches that the coating comprises a bioactive that is encapsulated via e.g., a microsphere or microparticle (paragraphs [0062], [0080], [0082] and [0083]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Thomson and Van Antwerp because both teach hydrophilic coatings comprising an active agent for the purpose of controlled release of said active agent. One of ordinary skill in the art would have been motivated to incorporate the microspheres of Van Antwerp into the coating of Thomson because Van Antwerp teaches that the microspheres assist in further modulating or controlling the release of the active agent (see Van Antwerp at paragraphs [0080] and [0083]). A practitioner would have reasonably expected a hydrophilic coating comprising microspheres containing a bioactive. Thus, in Thomson it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate microspheres as suggested by Van Antwerp.

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Claims 3, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (US 2002/0018884 A1) in view of Van Antwerp (US 2003/0031699 A1) and further in view of Pinchuk (USPN 5,229,431).

Thomson and Van Antwerp teach the elements discussed above.

Thomson and Van Antwerp are silent to including an agent into the scaffold as well as the particular scaffold material being polycarbonate polyurethane.

Pinchuk teaches a polycarbonate urethane foam suitable for medical prosthesis and implants (abstract). Said suitable medical prosthesis and implants include drug eluting matrices (col. 3, line 4).

One of ordinary skill in the art would have been motivated to include the particular material polycarbonate urethane because of its crack-resistant, elastomeric and pliable properties (abstract). A practitioner would have reasonably expected said material to withstand the stresses and degradation conditions once implanted in the body. One skilled in the art would have additionally expected inclusion of an agent within the matrix to effectively elute into the body. Thus, in Thomson and Van Antwerp, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular material polycarbonate urethane as well as an active agent in the scaffold as suggested by Pinchuk.

### ***Conclusion***

All claims have been rejected; no claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615